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UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Jeffrey W. Ruberti and Gavin J. C. Braithwaite  
Application No.: 10/771,852 Filed Date: February 4, 2004  
Confirmation No. 9743 Group: 1713 Examiner: Not Assigned  
For: Systems and Methods for Controlling and Forming Polymer Gels

CERTIFICATE OF MAILING	
I Hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450	
on June 7, 2004	Sharon R. Lloyd
Date	Signature
Sharon R. Lloyd	
Typed or printed name of person signing certificate	

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment or Mail Stop Missing Parts  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:  
☐ a Statement under 37 CFR 1.97(e), as checked below, or  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(More than 3 months after receipt of the International Search Report, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:  
☐ a Statement under 37 CFR 1.97(e), as checked below, and  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.  
(Filed after payment of issue fee)



Application No. 10/771,852

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☒ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Enclosed herewith is form PTO-1449:

- ☒ Copies of the cited references are enclosed.
- ☐ In accordance with 37 C.F.R. § 1.98 (d), copies of cited references ( ) are not enclosed as these references were entered in earlier application, [ ], to which the present application claims priority under 35 U.S.C. 120. The earlier application contains copies of the cited references.
- ☐ If copies of references [\*list references not enclosed\*] would benefit the Examiner of this case, the Examiner is invited to call the undersigned attorney and copies will be forwarded immediately.
- ☐ Listed references [ ] were cited in the enclosed International Search Report in a counterpart foreign application.

Concise Explanation Requirement (non-English references):

- ☐ The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
  - ☐ the explanation provided in the Specification.
  - ☐ submission of the enclosed International Search Report.
  - ☐ the enclosed English language abstract.

☐ Applicant requests that the following pending applications be considered:



U.S. Patent Application No. [ ], Publication No. [ ], Publication Date [ ],  
by [inventor(s)], filed [ ], Docket No.: [ ]

U.S. Patent Application No. [ ], Publication No. [ ], Publication Date [ ],  
by [inventor(s)], filed [ ], Docket No.: [ ]

U.S. Patent Application No. [ ], Publication No. [ ], Publication Date [ ],  
by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_  
Examiner

\_\_\_\_\_  
Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account No. 50-1935 in the amount of \$[ ]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account No. 50-1935.

Respectfully submitted,

BOWDITCH & DEWEY, LLP

By Monica Grewal

Monica Grewal

Date: June 7, 2004

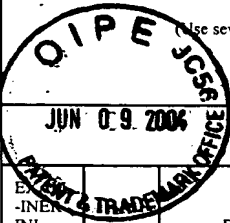
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PTO-1449 REPRODUCED  INFORMATION DISCLOSURE CITATION IN AN APPLICATION  JUNE 7, 2004  (Use several sheets if necessary)			ATTORNEY DOCKET NO. 301788.3002-102		APPLICATION NO. 10/771,852		
			APPLICANT Jeffrey W. Ruberti and Gavin J. C. Braithwaite				
			FILING DATE February 4, 2004		GROUP ART UNIT 1713		
U.S. PATENT DOCUMENTS							
EX- JIN- INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	3,875,302	1 Apr 1975	Inoue	426	1	
	AB	4,472,542	18 Sep 1984	Nambu	523	309	
	AC	4,772,287	Sep 20, 1988	Ray et al.	623	17	
	AD	4,904,260	Feb 27, 1990	Ray et al.	623	17	
	AE	5,047,055	Sep 10, 1991	Bao et al.	623	17	
	AF	5,071,437	Dec 10, 1991	Steffee	623	17	
	AG	5,260,066	Nov 9, 1993	Wood et al.	424	447	
	AH	5,288,503	Feb 22, 1994	Wood et al.	424	497	
	AI	5,534,028	Jul 9, 1996	Bao, et al.	623	17.16	
	AJ	5,976,186	Nov 2, 1999	Bao et al.	623	17	
	AK	5,981,826	9 Nov 1999	Ku et al	623	11	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AL	WO 01/12107 A1	22 Feb 2001	PCT			
	AM	WO 02/054978 A2	18 Jul 2002	PCT			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AR	AAOS, Musculoskeletal Conditions in the U.S., Feb 1992-1988, 1992, AAOS					
	AS	Bao, Q.B., & Yuan, H. A., "Nucleus Replacement," Spine, Vol. 27, No. 11, 2002, 1245-1247					
	AT	Bao, Q. & Yuan, H.A, "Prosthetic Disc Replacement: The Future?," Clinical Orthopaedics and Related Research, No. 394, pp 139-145, 2002					
	AU	Bao, Q. et al, "The artificial disc: theory, design and materials," Biomaterials Vol. 17, No. 12, (1996) 1157-1167					
	AV	Bray, J.C. & Merrill, E. W., "Poly(vinyl Alcohol) Hydrogels. Formation by Electron Beam Irradiation of Aqueous Solutions and Subsequent Crystallization," Journal of Applied Polymer Science, Vol. 17, pp 3779-3794, 1973					
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	AA2	6,231,605	May 15, 2001	Ku	623	11.11	
	AB2	6,264,695	Jul 21, 2001	Stoy	623	17.11	
	AC2	6,268,405	Jul 31, 2001	Yao et al.	523	113	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AN	EP 1 229 873 B1	14 Aug 2002	Europe			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AW	Bray, J.C. & Merrill, E. W., "Poly(vinyl alcohol) Hydrogels for Synthetic Articular Cartilage Material," Biomed. Mater. Res., Vol. 7, pp. 431-443 1973					
	AX	Choi, J. H., et al., "Rheological Properties of Syndiotacticity-Rich Ultrahigh Molecular Weight Poly(vinyl alcohol) Dilute Solution," Journal of Applied Polymer Science, Vol. 82, 569-576 (2001)					
	AY	Damshkaln, L. G., et al, "Study of Cryostructuration of Polymer Systems. XV. Freeze-Thaw-Induced Formation of Cryoprecipitate Matter from Low-Concentrated Aqueous Solutions of Poly(vinyl alcohol), Journal of Applied Polymer Science, Vol. 74, 1978-1986 (1999)					
	AZ	Darwis, D., et al, "Characterization of poly(vinyl alcohol) hydrogel for prosthetic intervertebral disc nucleus," Radiation Physics and Chemistry 63 (2002) 539-542					
	AR2	de Gennes, P.G., "Scaling Concepts in Polymer Physics," First ed. 1979: Cornell University Press, 72, 113-114					
	AS2	Diwan, A. D. et al, "Current Concepts in Intervertebral Disk Restoration," Tissue Engineering in Orthopedic Surgery, Vol. 31, No. 3, pp 453-464, July 2000					
	AT2	Doehring, T.C. et al, "Cyclic Load-Displacement Characteristics of Lumbar Functional Spinal Units," 46 <sup>th</sup> Annual Meeting, Orthopaedic Research Society, March 12-15, 2000					
	AU2	Elias, H.G., "Theta Solvents," Brandrup, J. and E. H. Immergut, Polymer Handbook 3rd Ed., John Wiley & Sons, NY 1989					
	AV2	Flory, P.J., "Principles of Polymer Chemistry," 1953, Ithaca and London: Cornell University Press					
	AW2	Gomes, K. et al, "The Effect of Dehydration History on Associating Hydrogels for Nucleus Pulposus Replacement," Society for Biomaterials, 28 <sup>th</sup> Annual Meeting Transactions, 2002					
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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AX2	Griffith, S. L. et al, "A Multicenter Retrospective Study of the Clinical Results of the LINK <sup>®</sup> SB Charité Intervertebral Prosthesis," SPINE, Vol. 19, No. 16, 1842-1849, 1994					
	AY2	Hassan, C., M., & Peppas, N.A., "Cellular PVA Hydrogels Produced by Freeze/Thawing," Journal of Applied Polymer Science, Vol. 76, 2075-2078 (2000)					
	AZ2	Hassan C., M. et al, "Diffusional characteristics of freeze/thawed poly(vinyl alcohol) hydrogels: Applications to protein controlled release from multilaminate devices," European Journal of Pharmaceutics and Biopharmaceutics 49 (2000) 161-165					
	AR3	Hassan, C., M. et al., "Modeling of crystal dissolution of poly(vinyl alcohol) gels produced by freezing/thawing process," Polymer 41 (2000) 6729-6739					
	AS3	Hassan C. M. & Peppas N. A., "Structure and Morphology of Freeze/Thawed PVA Hydrogels," Macromolecule, Vol. 33, No. 7, 2472-2479, 2000					
	AT3	Hickey, A. S. & Peppas N.A., "Solute diffusion in poly(vinyl alcohol)/poly(acrylic acid) composite membranes prepared by freezing/thawing techniques," Polymer, Vol. 38 No. 24 1997 5931-5936					
	AU3	Hong, P. et al, "Effects of Mixed Solvent on Gelation of Poly(vinyl alcohol) Solutions," Journal of Applied Polymer Science, Vol 79, Issue: 6, Date: 7 February 2001, Pages: 1113-1120					
	AV3	Hóng, P, et al, "Solvent Effect on Structural Change of Poly(vinyl alcohol) Physical Gels," Journal of Applied Polymer Science, Vol. 69, 2477-2486 (1998)					
	AW3	Juarez, K.K. & An, H.S., "Artificial Disc Replacement," Spineuniverse.com					
	AX3	Kawanishi K. et al, "Thermodynamic consideration of the sol-gel transition in polymer solutions," 35 <sup>th</sup> Annual Meeting of the Society of Polymer Science, Japan, 1986					
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	AY3	Li, J. K., et al, "Poly(vinyl alcohol) nanoparticles prepared by freezing-thawing process for protein/peptide drug delivery," Journal of Controlled Release 56 (1998) 117-126					
	AZ3	Lozinskii V. I. & Savina I. N., "Study of Cryostructuring of Polymer Systems: 22. Composite Poly(vinyl alcohol) Cryogels Filled with Dispersed Particles of Various Degrees of Hydrophilicity/Hydrophobicity," Colloid Journal, Vol. 64, No. 3, 2002, 336-343					
	AR4	Lozinsky, V. I., et al, "Study of Cryostructuring of Polymer Systems, XIV. Poly(vinyl alcohol) Cryogels: Apparent Yield of the Freeze-Thaw-Induced Gelation of Concentrated Aqueous Solutions of the Polymer," Journal of Applied Polymer Science, Vol. 77, 1822-1831 (2000)					
	AS4	Lozinsky, V. I. & Damshkaln L. G., "Study of Cryostructuring of Polymer Systems. XVII. Poly(vinyl alcohol) Cryogels: Dynamics of the Cryotropic Gel Formation," Journal of Applied Polymer Science, Vol 77, 2017-2023 (2000)					
	AT4	Lozinsky, V. I. et al, "Swelling behavior of poly(vinyl alcohol) cryogels employed as matrices for cell immobilization), Enzyme Microb. Technol, Vol. 18, 561-569, 1996					
	AU4	Marolongo, M., et al, "Novel Hydrogel Copolymers for Intervertebral Disc Replacement," Sixth World Biomaterials Congress Transactions, 2000					
	AV4	Mike, C., "FDA Approves Bone Graft," 2002, <a href="http://www.news.wisc.edu/view.html?get=7640">http://www.news.wisc.edu/view.html?get=7640</a>					
	AW4	Mongia, N.K., et al, "Mucoadhesive poly(vinyl alcohol) hydrogels produced by freezing/thawing processes: Applications in the development of wound healing systems," J. Biomater. Sci, Polymer Edn, Vol. 7, No. 12, pp. 1055-1064 (1996)					
	AX4	Nakane, K., et al., "Properties and Structure of Poly(vinyl alcohol)/Silica Composites," Journal of Applied Polymer Science, Vol. 74, 133-138 (1999)					
	AY4	Narasimhan, B. & Peppas, N.A., "Molecular Analysis of Drug Delivery Systems Controlled by Dissolution of the Polymer Carrier," Journal of Pharmaceutical Sciences, Vol. 86, No. 3, March 1997					
	AZ4	"New Implants Offer Relief of Spine" 2001, Medical Device and Diagnostic Industry					
	AR5	Norton, B. K, et al, "Mechanical Evaluation of a Structural Hydrogel for Use as a Spinal Disc Nucleus," Sixth World Biomaterials Congress Transactions, 2000					
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	AS5	Ogata, N., et al., "Poly(vinyl alcohol)-clay and Poly (ethylene oxide)-clay Blends Prepared Using Water as Solvent," Journal of Applied Polymer Science, Vol. 66, 573-581 (1997)					
	AT5	Onuki, A. & Puri, S., "Spinodal decomposition in gels," Physical Review E, Vol. 59, No. 2, Feb. 1999, R1331-R1334					
	AU5	Oka, M. et al, "Development of artificial articular cartilage," Proc Instn Mech Engrs Vol. 214 Part H, 59-68, 2000					
	AV5	Peppas, N.A. & Stauffer, S. R., "Reinforced uncrosslinked poly (vinyl alcohol) gels produced by cyclic freezing-thawing processes: a short review," Journal of Controlled Release, 16 (1991) 305-310					
	AW5	Peppas, N. A. et al, "Physicochemical Foundations and Structural Design of Hydrogels in Medicine and Biology," Annu. Rev. Biomed. Eng., 02:9-20, 2000					
	AX5	Stammen, J. A., et al., "Mechanical properties of a novel PVA hydrogel in shear and unconfined compression," Biomaterials, 2001 Apr 22 (8), 799-806, abstract only					
	AY5	Stawhecker K.E. & Manias E., "AFM of Poly(vinyl alcohol) Crystals Next to an Inorganic Surface," Macromolecules, 2001, 34, 8475-8482					
	AZ5	Strawhecker, K.E. & Manias, E., "Structure and Properties of Poly(vinyl alcohol)/NA+ Montmorillonite Nanocomposites," Chem. Mater, 2000, 12, 2943-2949					
	AR6	Takahashi, N., et al, "Effects of cononsolvency on gelation of poly(vinyl alcohol) in mixed solvents of dimethyl sulfoxide and water," Polymer 44 (2003) 4075-4078					
	AS6	Takeshita, H. et al, "Small-angle neutron scattering studies on network structure of transparent and opaque PVA gels," Physica B 311 (2002) 78-83					
	AT6	Takeshita, H., et al, "Spinodal Decomposition and Syneresis of PVA Gel," Macromolecules 2001, 34, 7894-7898					
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	AU6	Takeshita, H. et al, "Gelation Process and Phase Separation of PVA Solutions as Studied by a Light Scattering Technique," Macromolecules 32, 7815-7819, 1999					
	AV6	UPMC Surgeons Implanting Metal Cages into the Spine to Treat Chronic Low Back Pain, Neurosurgery News, 1999, University of Pittsburgh					
	AW6	Urushizaki, F. et al, "Swelling and mechanical properties of poly(vinyl alcohol) hydrogels," International Journal of Pharmaceutics, 58 135-142, 1990					
	AX6	Vago, R., "Novel Natural Materials for Bone Substitutes and Hard Tissue Remodeling," <a href="http://www.bgu.ac.il/bgn/bone.html">http://www.bgu.ac.il/bgn/bone.html</a>					
	AY6	Wiesel, S.W. et al, "Industrial Low-Back Pain-A Prospective Evaluation of a Standardized Diagnostic and Treatment Protocol," SPINE, Vol. 9, No. 2, 199-203, 1984					
	AZ6	Wilke, H-J, et al, "Prosthetic Disc Nucleus Restores the Flexibility and Disc Height of a Disc After Nucleotomy," Sixth World Biomaterials Congress Transactions, 2000					
	AR7	Willcox, P. J., et al, "Microstructure of Poly(vinyl alcohol) Hydrogels Produced by Freeze/Thaw Cycling," Journal of Polymer Science: Part B: Polymer Physics, Vol. 37, 3438-3454 (1999)					
	AS7	Yamaura K., et al, "Gels of Syndiotacticity-Rich Poly(vinyl Alcohol)-Water/Dimethyl Sulfoxide or - Water/Ethylene Glycol Solutions," Journal of Applied Polymer Science, Vol. 34, 2347-2354 (1987)					
	AT7	Yamaura, K. et al., "Properties of Gels Obtained by Freezing/Thawing of Poly(vinyl Alcohol)/Water/Dimethyl Sulfoxide Solutions," Journal of Applied Polymer Science, Vol. 37, 2709-2718 (1989)					
	AU7	Yokoyama, F., et al, "Morphology and structure of highly elastic poly (vinyl alcohol) hydrogel prepared by repeated freezing-and-melting," Colloid & Polymer Sci 264: 595-601 (1986)					
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	AV7	Yu, Y, et al, "Preparation and properties of poly (vinyl alcohol) clay nanocomposite materials," Polymer 44 (2003) 3553-3560					
	AW7	Zeegers, W. S., et al, "Artificial disc replacement with the modular type SB Charit III: 2-year results in 50 prospectively studied patients," Eur Spine J, 8:210-217, 1999					
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